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EXAMINER
JAGOE, DONNA A

ART UNIT	PAPER NUMBER
1614	4

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/075,715	Applicant(s) CHOPP ET AL.	
	Examiner Donna Jagoe	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1 to 8 are presented for examination.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A (1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

New formal drawings are required in this application. See PTO-948 for Draftsperson's Patent Drawing Review. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the Patent and Trademark Office no longer prepares new drawings.

Claim Objections

Claims 7 and 8 are objected to because of the following informalities:
The recitation of the treatment of individuals "in need" of the treatment of a certain condition is missing. Appropriate correction is required. A physician will typically examine many patients with various pathologies, and only some will have a particular

disease requiring a particular treatment. It has been traditional in United States practice to recite the treatment of individuals "in need" of the treatment of a certain condition so as to indicate that particular subset of patients actually in need of intervention; an alternative is to recite the treatment of an individual "suffering from" a given disease. Accordingly, the following format is preferred for claiming methods of treating: "A method for treating disease X comprising administering to an individual suffering from/in need of such treatment an effective amount of agent Y". Claims not specifying the subset of patients to be treated in this manner are generally viewed as being anticipated by any prior art method using a given agent since they read on administration to the general population and not a specified subset requiring treatment.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 contains the trademark/trade names Lipitor®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope

is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe an HMG CoA reductase inhibitor, atorvastatin and, accordingly, the identification/description is indefinite. It is suggested that the claim be amended to recite "the neurogenesis promoter according to claim 4, wherein said nitric oxide donor is selected from the group consisting essentially of phosphodiesterase inhibitors, L-arginine, sildenafil and atorvastatin" to obviate the rejection.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Moskowitz U.S. Patent No. 5,385,940 (A).

Claims 1 and 6-8 are drawn to a method of promoting, augmenting the production of neurons and increasing neurological function (neurogenesis) comprising administering a therapeutic amount of a nitric oxide donor compound to a patient in need of such treatment. Claims 2-5 are drawn to a compound that is a nitric oxide

donor and augments nitric oxide in a tissue such as l-arginine in a pharmaceutically acceptable carrier for promoting neurogenesis.

Moskowitz teaches a method of treating stroke (see abstract) and the resulting neural damage (column 1, lines 34-44) comprising administration of nitric oxide-releasing compounds such as L-arginine (column 1, line 65 to column 2, line 12). The therapeutic amount of L-arginine, 10 to 500 mg/kg, is administered parenterally (column 3, lines 63-68). Moskowitz teaches the nitric oxide releasing compound decreases the infarct size following experimental stroke wherein the infarct areas were significantly reduced (column 5, line 44 to column 7, line 18). Since the agent, L-arginine, is being administered under the same conditions in the prior art as in the instant claims, the general promotion of neurogenesis must inevitably occur with each use. The compound or neurogenesis promoter of claims 2-5 in a pharmaceutically acceptable carrier is recited in column 2, lines 41-51 wherein L-arginine is prepared in a sterile solution for administration to a patient.

Regarding claims 2-5 claiming a compound for promoting neurogenesis such as a PDE inhibitor, L-arginine, sildenafil and lipitor, it is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable. See In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) ("The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from prior art, can not impart patentability to claims to the known composition."); Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 782, 227 USPQ 773, 778 (Fed. Cir. 1985) (composition claim

reciting a newly discovered property of an old alloy did not satisfy section 102 because the alloy itself was not new); In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claim patentable); In re Zierden, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969) ("mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable."); In re Sinex, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962) (statement of intended use in an apparatus claim failed to distinguish over the prior art apparatus); In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 162 (CCPA 1957) ("the grant of a patent on a composition or a machine cannot be predicated on a new use of that machine or composition"); In re Benner, 174 F.2d 938, 942, 82 USPQ 49, 53 (CCPA 1949) ("no provision has been made in the patent statutes for granting a patent upon an old product based solely upon discovery of a new use for such product"). The intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Since PDE inhibitor's, L-arginine, sildenafil and atorvastatin is capable of performing the intended use of promoting neurogenesis by augmenting nitric oxide in the tissue, then it meets the claim.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Liao, U.S. Patent No. 6,423,751 (B).

Claims 1 and 6-8 are drawn to a method of promoting, augmenting the production of neurons and increasing neurological function (neurogenesis) comprising administering a therapeutic amount of a nitric oxide donor compound to a patient in need of such treatment. Claims 2-5 are drawn to a compound that is a nitric oxide donor and augments nitric oxide in a tissue such as Lipitor in a pharmaceutically acceptable carrier for promoting neurogenesis.

Liao teaches upregulation of endothelial cell nitric oxide synthase expression (column 3, lines 24-31) by administration of, *inter alia*, HMG CoA reductase inhibitors such as atorvastatin (column 15, line 38 to column 16, line 12). Liao teaches that a surprising connection was made in connection with the treatment of ischemic stroke wherein brain injury reduction is measured by determining a reduction in the infarct size in the treated versus the control groups. Cerebral blood flow was better in the treated animals and it is believed that the positive results are attributable to the upregulation of

endothelial cell nitric oxide synthase activity (column 8, line 59 to column 9, line 8). Although Liao does not recite augmenting production of neurons and increasing neurological function and cognitive function, since the same agent is being administered under the same conditions in the prior art as in the instant claims, the general promotion of neurogenesis must inevitably occur in each case.

Regarding claims 2-5 claiming a compound for promoting neurogenesis such as a PDE inhibitor, L-arginine, sildenafil and Lipitor, it is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable. See In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) ("The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from prior art, can not impart patentability to claims to the known composition."); Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 782, 227 USPQ 773, 778 (Fed. Cir. 1985) (composition claim reciting a newly discovered property of an old alloy did not satisfy section 102 because the alloy itself was not new); In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claim patentable); In re Zierden, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969) ("mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable."); In re Sinex, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962) (statement of intended use in an apparatus claim failed to distinguish over the prior art apparatus); In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 162 (CCPA 1957) ("the grant of a patent on a composition or a machine cannot be

predicated on a new use of that machine or composition"); In re Benner, 174 F.2d 938, 942, 82 USPQ 49, 53 (CCPA 1949) ("no provision has been made in the patent statutes for granting a patent upon an old product based solely upon discovery of a new use for such product"). The intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Since the atorvastatin of the patent is capable of performing the intended use of promoting neurogenesis by augmenting nitric oxide in the tissue, then it meets the claim.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Donna Jagoe
Patent Examiner
Art Unit 1614

dj
May 28, 2003